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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/291,894 04/13/99 COLLINS

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EXAMINER

BRUMBACK, B

ART UNIT

PAPER NUMBER

1642

6

DATE MAILED:

06/07/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/291,894

Applicant(s)

Collins et al.

Examiner  
Brenda Brumback

Group Art Unit  
1642



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-65 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-65 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, 6-10, 21, 35, and 46-51 drawn to chimeric human RSV comprising RSV A combined with human RSV B, classified in class 424, subclass 199.1 or 211.1.
  - II. Claims 1, 4, 5, and 11, drawn to chimeric RSV wherein the heterologous gene is selected from NS1, NS2, N, P, M, SH, M1(ORF1), M2(ORF2), L, F, and G, classified in 424, subclass 199.1 or 211.1.
  - III. Claims 1, 12, 13, 18-20, and 22, drawn to chimeric RSV further modified by attenuating mutations present within a panel of biologically derived mutant RSV strains, classified in class, 424 subclass 199.1 or 211.1.
  - IV. Claims 1, 12, 14, 20, and 22, drawn to chimeric RSV incorporating temperature sensitive mutations, classified in class 424, subclass 199.1 or 211.1.
  - V. Claims 1, 12, 15, 20, and 22, drawn to chimeric RSV incorporating mutations from cold-passaged attenuated RSV, classified in class 424, subclass 199.1 or 211.1.

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- VI. Claims 1, 16, 17, 20, and 22, drawn to chimeric RSV comprising substituted F and G genes and further modified to incorporate attenuating point mutations, classified in class 424, subclass 199.1 or 211.1.
- VII. Claims 1 and 22-24, drawn to chimeric RSV further comprising a nucleotide modification specifying a phenotypic change, wherein a SH, NS1, NS2, M2ORF2, or G gene is deleted, classified in class 424, subclass 199.1 or 211.1.
- VIII. Claims 1, 22, and 25-29, drawn to chimeric RSV further comprising a deletion, insertion, substitution or rearrangement of a cis-acting regulatory sequence, classified in class 424, subclass 199.1 or 211.1.
- IX. Claims 1, 22, and 30-33, drawn to chimeric RSV incorporating a non-RSV gene, classified in class 424, subclass 199.1 or 211.1.
- X. Claims 1 and 34, drawn to chimeric RSV comprising human RSV combined with bovine or murine RSV, classified in class 424, subclass 199.1 or 211.1.
- XI. Claims 1 and 36, drawn to chimeric RSV which is a subviral particle, classified in class 424, subclass 199.1 or 211.1.
- XII. Claims 1 and 37-45, drawn to methods of stimulating the immune system, classified in class 424, subclass 199.1 or 211.1.
- XIII. Claims 52- 55 drawn to an isolated polynucleotide molecule comprising a chimeric RSV genome combined with a heterologous gene, wherein the heterologous gene

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encodes a RSV F, G, or SH glycoprotein, classified in class 424, subclass 199.1 or 211.1.

XIV. Claims 52, and 56-60, drawn to an isolated polynucleotide molecule comprising a chimeric RSV genome of subgroup A combined with a heterologous gene from subgroup B, classified in class 424, subclass 199.1 or 211.1.

XV. Claims 52 and 61-63, drawn to an isolated polynucleotide molecule comprising a chimeric RSV genome and further comprising a nucleotide modification specifying a phenotypic change, classified in class 424, subclass 199.1 or 211.1.

XVI. Claims 64 and 65, drawn to methods for producing an infectious attenuated chimeric RSV, classified in class 424, subclass 199.1 or 211.1.

2. The inventions are distinct, each from the other because of the following reasons:

The products of groups I-XI, and XIII-XV have different structures and different immunological properties.

Inventions I and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the chimeric RSV of Group I can be used in the materially different processes of diagnostic testing and affinity purification of antibodies.

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The methods of Groups XII and XVI have different method steps and are for different purposes.

It is noted that certain of the claims appear in multiple groups. Claims which appear in more than one group will be examined with the elected group to the extent that they read on that group.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Due to the complexity of the claims, the restriction requirement is in writing. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

June 5, 2000

*Brenda Brumback*  
Brenda Brumback,  
Patent Examiner